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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,619	12/22/2000	Wayne L. Ryan	1003-015	1867

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT	PAPER NUMBER
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1641

14

DATE MAILED: 05/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/747,619

Applicant(s)

RYAN ET AL.

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,9-11 and 35-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,9-11 and 35-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/12/01 has been entered.
2. The amendments filed on 12/12/01 and 2/14/02 have been received. Claims 1, 9-11 and 35-42 are pending.
3. Newly submitted claim 41 is misnumbered and has been renumbered to 42. Applicant's attention is directed to 37 CFR 1.126 which states "the original numbering of the claims must be preserved throughout the prosecution. When claims are canceled the remaining claims must not be renumbered. When claims are added, they must be numbered by the applicant consecutively beginning with the number next following the highest numbered claim previously presented (whether entered or not)."
4. The text of those US codes not found in this office action may be found in a previous office action.

Claim Rejections - 35 USC § 112

5. Claim 35-41 are vague and indefinite rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 39, 40 and 41 are vague and indefinite with respect to the recitation of the proportions of the ingredients. The claims recites "parts by weight" whereas the specification teaches "percent by weight". It is suggested that the claims be amended to recite "percent by weight" for clarity.

Claims 35-38 are indefinite because it depends on canceled claim 5.

Claim Rejections - 35 USC § 103

6. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al (USP 5,529,933) in view of Ryan (USP 5,460,797).

Young discloses a hematology control reagent composition comprising an aqueous solution of plasma substance. When the composition is subject to a lytic reagent, the composition permits the lytic reaction to occur for the red blood cells in the control product. See column 6, lines 20-56. Fresh red blood cells samples may be treated with a composition comprising serum substances as a processing aid. Serum substances comprise cholesterol, cholesterol esters, lipoprotein and phospholipids and mixtures thereof. See column 8, lines 11-57. Young also discloses a saponin-based lytic system in the composition. See column 12, lines 52-55; and column 13, lines 17-20. Specifically, Young discloses a composition for preparing leukocytes in whole blood comprising a lytic agent, a fixative such as formaldehyde, a serum component and a suitable stabilizer.

Young et al differ from the instant invention in failing to teach the use of a preservative comprising diazolidinyl urea (DU).

Ryan discloses a fixative solution for tissue cells comprising suspending material to be fixed or stabilized in an agent comprising diazolidinyl urea, imidazolidinyl urea and

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oxazolidines, etc. See column 3, lines 18-60. Ryan specifically discloses that the agents are preferred over formaldehyde and that the agents have extremely low toxicity, low flammability and thus do not present a fire hazard. See column 4, lines 13-57. Ryan also discloses a leukocyte positive control check for antigen-antibody studies in flow cytometry. See column 10, lines 44-65 and column 11, lines 7-58.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the DU taught by Ryan in the composition of Young because Ryan clearly teaches the advantages of using diazolidinyl urea, imidazolidinyl and oxazolidine instead of formaldehyde. Specifically, DU has extremely low toxicity, low flammability and thus do not present a fire hazard. DU is also advantageous because of its ability to preserve antigenic properties of the samples being evaluated. A skilled artisan would have had a reasonable expectation of success in using the DU taught by Ryan in the composition of Young because Young teaches the use of stabilizer and preservatives including formaldehyde and Ryan teaches the advantage of DU as a substitute for formaldehyde.

Allowable Subject Matter

7. The following is a statement of reasons for the indication of allowable subject matter: claims 1, 9-11, 39-41 are allowable over the prior art of record because the prior art of record, specifically, Young and Ryan, do not teach a reagent composition comprising, in a single mixture, a lysing agent, a lipoprotein and a preservative (specifically diazolidinyl urea, imidazolidinyl urea or oxazolidine).
8. Claims 39-41 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

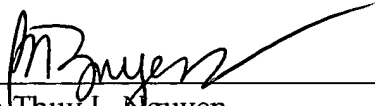
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Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Monday, Wednesday and Thursday from 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bao-Thuy L. Nguyen
Primary Examiner
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May 2, 2003